
NEWS RELEASE

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GREGG COMMENTS ON FDA PEDIATRICS ANNOUNCEMENT

WASHINGTON— U.S. Senator Judd Gregg (R-NH), incoming Chairman of the Senate Health, Education, Labor and Pensions Committee, today commented on the Food and Drug Administration's decision not to appeal a court decision striking down a rule created by the Clinton Administration that required drug companies to conduct studies on children regarding medications.

Senator Gregg stated, "Children are unique among all other groups of individuals who may use medications because they are so vulnerable and do not yet have fully-matured internal organs. They require special considerations to ensure that their particular needs and conditions are studied and well-understood before they are exposed to potentially harmful drugs. The current system that provides Americans with valuable information about the drugs that their children are taking has been extremely useful and it should be continued. Unfortunately, with the October court decision eliminating the program, that system is no longer available, having been established without statutory authority.

"As the incoming Chairman of the Senate Health Committee, I look forward to working with my friends in the children's public health arena and with the Administration to ensure that Congress provides the needed authority as soon as possible. I anticipate bringing such authorizing legislation before the Committee in the first part of the year with bipartisan support."

The Clinton Rule is crafted of two components that allow the FDA to compel companies to conduct studies on children in compelling circumstances. First, for new drugs, a company must coordinate early in a drug's development to assess the extent to which pediatric uses will be involved and studies will be necessary. Second, for already-marketed drugs, the FDA may order a company to do additional studies on the drug.

In December 2001, Congress passed the Best Pharmaceuticals for Children incentives statute that reauthorized the successful program which gives drug companies six months of market exclusivity if they conduct studies on pediatric uses of drugs. The program is voluntary and only triggered by an FDA request for the study. The program would expire in October 2007.

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